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(71) Applicant: WARNER-LAMBERT COMPANY [US/US]; 201 Tabor Road, Morris Plains, NJ 07950 (US).			
(72) Inventors: CARLIN, Edward, James; 794 5th Street, Secaucus, NJ 07094 (US). BARCELON, Shirley, A.; 44 K53 Center Grove Road, Randolph, NJ 07869 (US). CHU, Paula; 19 McCann Mill Road, Pottersville, NJ 07979 (US).			
(74) Agents: RYAN, M., Andrea; Warner-Lambert Company, 201 Tabor Road, Morris Plains, NJ 07950 (US) et al.			
(54) Title: COMPOSITIONS CAPABLE OF MASKING ASTRINGENT TASTE SENSATIONS			
(57) Abstract			
This invention provides compositions that are capable of masking astringent taste sensations experienced after the introduction into the mouth of breath freshening agents and/or anti-microbial agents, or certain materials capable of providing dietary, nutritional, medicinal, therapeutic, oral hygiene and the like assistance.			

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TITLE

**COMPOSITIONS CAPABLE OF MASKING  
ASTRINGENT TASTE SENSATIONS**

5

BACKGROUND OF THE INVENTION

Field of the Invention

- 10 The present invention is directed to compositions capable of masking astringent taste sensations. These composition may be employed in products containing certain materials that impart astringency, which products are intended for introduction into the mouth  
15 for purposes such as dietary, nutritional, medicinal, therapeutic, oral hygiene and the like.

Discussion of Prior Art

- 20 For many years, manufacturers of oral hygiene products have formulated products whose intended purpose is to effectively prevent or reduce mouth odors. Many of the same manufactures have also formulated products whose intended purpose is to prevent gingivitis and retard  
25 the growth of dental plaque. Such products include mouthwashes and rinses, dentifrices like toothpastes and dental gels, chewing gums, lozenges and the like.

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Typically, ingredients such as breath freshening agents like poly-valent metal cations (e.g., zinc salts) have been added to those oral hygiene products to control oral odors and bad breath associated therewith which

- 5 may accompany the ingestion of, for instance, garlic and/or onions. Zinc salts have been found to be particularly effective in controlling such oral odors and bad breath. Zinc salts, as dicationic ions, are capable of complexing with elements found in compounds
- 10 which tend to cause the emanation of oral odors, such as sulfur compounds from garlic and onions. Zinc salts are also capable of adhering to the mucus membranes in the mouth. Such adherence prolongs their presence therein, and allows the dicationic zinc salts to be
- 15 available for complexing with such odor-causing elements.

Presently, manufacturers of oral hygiene products employ zinc salts as a breath freshening agent in

- 20 certain products, such as mouthwashes and rinses, to assist in controlling bad breath. The amount so employed is ordinarily up to about 0.2%. It would be desirable to increase that amount to enhance the activity of the breath freshening agent in the mouth.
- 25 By so doing, the breath freshening aspect of the oral hygiene product should be more effective and/or last for extended periods of time. However, even at the 0.2% level, zinc salts tend to impart an unpleasant and offensive astringent taste sensation that has been
- 30 described as biting and drying. Hence, at levels greater than that, the astringent taste sensation is even more pronounced and unpleasant.

- 35 The inventors are aware of efforts to taste-mask the unpleasant flavor of zinc. In one such work, a delivery system was established for food additives and nutritional supplements which employs the zinc compound

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- as a core material, with a first, hydrophilic coating and a second, hydrophobic coating, and an excipient for delivery. U.S. Patent No. 5,059,416 (Cherukuri). In another such work, a method for masking the flavor of 5 compositions for oral absorption is disclosed, which compositions contain ionizable zinc compounds and anethole as the masking agent. U.S. Patent No. 5,002,970 (Eby, III).
- 10 Other ingredients, such as anti-microbial agents like quaternary ammonium compounds, are also presently employed by manufacturers of oral hygiene products in certain of such products to assist in retarding dental plaque growth. It would also be desirable to increase 15 the amount of those anti-microbial agents to provide a higher dosage and a more effective hygienic function in the mouth. However, at elevated levels, certain of those anti-microbial agents also tend to impart astringent taste sensations.
- 20 It would be desirable to provide increased amounts of breath freshening agents and/or anti-microbial agents in oral hygiene products to enhance the effectiveness and/or prolong the activity of those agents in the 25 mouth without unpleasant and unwelcome temporal side effects.
- It would also be desirable to provide increased amounts of certain poly-valent metal cations like zinc salts in 30 products to provide enhanced dietary, nutritional, medicinal, therapeutic or hygienic value through the increased dosage, without any such unpleasant side effects.
- 35 Therefore, the need exists for a way to mask the unwanted temporal side-effects (e.g., astringency) imparted by the breath freshening agents and/or anti-

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microbial agents contained in oral hygiene products, particularly where an increased dosage of those agents is desirably employed. The need also exists for a way to mask the unwanted temporal side-effects imparted by  
5 products containing certain poly-valent metal cations (like zinc salts) intended for introduction into the mouth and/or ingestion, such as in dietary and nutritional supplements, medicaments, and therapeutic and hygienic products.

10

SUMMARY OF THE INVENTION

This invention provides compositions capable of masking unpleasant astringent taste sensations, such as those  
15 experienced in the mouth after the introduction of certain materials therein. The compositions of this invention are prepared from the combination of a humectant component and a salt component.  
20 More specifically, many consumers of oral hygiene products containing certain breath freshening agents (e.g., poly-valent metal cations like zinc compounds) and/or anti-microbial agents (e.g., benzoic acid compounds) typically experience astringent taste  
25 sensations when such products are introduced into the mouth. In addition, the introduction into the mouth of certain poly-valent metal cations like zinc salts for dietary and nutritional purposes, like mineral supplements or for medicinal and therapeutic purposes,  
30 may also provide similar unpleasant astringent taste sensations.

This invention also provides a method of using a composition comprising a humectant component and a salt  
35 component to mask astringent taste sensations associated with certain materials which have been introduced into the mouth.

### DETAILED DESCRIPTION OF THE INVENTION

The masking compositions of this invention comprise a humectant component and a salt component, which, in combination, are capable of masking the astringency of certain breath freshening agents and/or anti-microbial agents when such agents are introduced into the mouth. Typically, the breath freshening agents are poly-valent metal cations. Poly-valent metal cations may also be introduced into the mouth as dietary and nutritional supplements, medicaments, or therapeutic and hygienic products. The compositions of this invention are well-suited to mask the astringency of these products when they too are introduced into the mouth.

15

The humectant component in the masking compositions of this invention is included to counteract the residual dryness ordinarily experienced in the mouth after use of oral hygiene products containing elevated levels of certain breath freshening agents and/or anti-microbial agents that are astringent. Suitable humectants for use in these masking compositions include, for example, glycerin, sorbitol, propylene, mono- and di-glycerides of fatty acids, pectins and combinations thereof.

Masking compositions prepared with glycerin as a humectant component have been described as leaving a "warming" feeling in the mouth after an oral hygiene product containing such masking compositions has been introduced into the mouth. Such masking compositions may, therefore, be suitably employed in products flavored, for instance, with wintergreen flavoring agents. Masking compositions prepared with sorbitol as a humectant component have been described as leaving a "cooling" feeling in the mouth after an oral hygiene product containing such masking compositions has been introduced into the mouth. Such masking compositions

may, therefore, be suitably employed in products flavored, for instance, with mint flavoring agents.

- The salt component in the masking compositions is included therein to counter the residual biting feeling ordinarily experienced in the mouth after use of oral hygiene products containing elevated levels of certain breath freshening agents and/or anti-microbial agents that are astringent. Suitable salts for use in these masking compositions include, for example, sodium chloride, potassium chloride, sodium bicarbonate, potassium bicarbonate, sodium carbonate, potassium carbonate and combinations thereof.
- The poly-valent metal cations employed as breath freshening agents whose astringency may be effectively masked by the compositions of the present invention, particularly when employed at elevated levels, include, but are not limited to, zinc salts like zinc chloride, zinc salicylate and zinc gluconate, silver salts like silver nitrate and silver gluconate, and combinations thereof.
- The anti-microbial agents whose astringency may be effectively masked by the compositions of the present invention, particularly when employed at elevated levels, include benzoic acid and derivatives thereof, and other anti-microbial agents possessing similar taste attributes and combinations thereof. Still other anti-microbial agents commonly employed in oral hygiene products, which are said to contribute more of a bitter taste sensation than an astringent taste sensation may also benefit from the use of the masking compositions of this invention. Such anti-microbial agents, include quaternary ammonium compounds such as alkyl pyridinium halides like cetyl pyridinium chloride, benzethonium chloride and benzalkonium chloride, bisbiguanides like

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chlorhexidene [1,1'-hexamethylenebis(5-(4-chlorophenyl)biguanide)] and combinations thereof.

In oral hygiene products, the humectant should be  
5 employed in an amount within the range of about 20% to  
about 50% by weight of the total weight of the vehicle  
chosen to deliver the active oral hygiene ingredients.  
Preferably, and particularly in a liquid form such as  
mouthwash or mouth rinse formulations, the amount of  
10 the humectant itself should be within the range of from  
about 20 to about 40% by weight, with about 35% by  
weight being preferred, of the total weight of the oral  
hygiene product in which it is employed. The ratio of  
the humectant component to the salt in the masking  
15 composition should be within the range of from about  
99.99-99.00% humectant to about 0.01-1.00% salt.  
Accordingly, the masking compositions of this invention  
are employed approximately within the ranges referred  
to above.

20 The masking compositions of this invention may be  
employed in a variety of products, which products may  
be prepared in a variety of forms -- that is, the  
vehicle through which the active ingredients and other  
25 ingredients are introduced into the mouth. For  
instance, dietary, nutritional, medicinal, therapeutic  
and hygienic products may be administered in solid or  
liquid form. Because of the amount of humectant  
included in the masking compositions of this invention,  
30 it may be preferable to employ the inventive  
compositions of this application in a liquid delivery  
form. However, certain products in solid form may also  
benefit from the capabilities of the masking  
compositions of this invention, particularly when such  
35 solid products are dentifrices like pastes or gels  
(e.g., toothpastes or dental gels, respectively),  
chewing gums, chewable confections or lozenges.

The delivery vehicles may be chosen according to the desired purpose of administering such compounds -- e.g., supplementing dietary and nutritional requirements, providing medicinal or therapeutic relief 5 or providing oral hygiene treatments. Accordingly, the masking compositions of this invention, which effectively mask the unpleasant oral astringency associated with compounds administered for such purposes, should also be capable of being introduced 10 into the mouth in the recited delivery vehicles.

Liquid Delivery Vehicles

Liquid delivery vehicles, such as mouthwashes, rinses, 15 sprays and the like, may be used to introduce and deliver breath freshening agents and/or anti-microbial agents into mouth. In addition, liquid delivery vehicles may be used to deliver compounds, such as poly-valent cations like zinc salts, into the mouth for 20 a variety of intended purposes, such as those described herein.

When a masking composition according to this invention is desirably included in a liquid vehicle for delivery 25 into the mouth, the masking composition (or the individual components thereof) may be mixed with the particular oral hygiene ingredients, together with a liquid base to form a solution, suspension or dispersion. The liquid base may comprise water, 30 ethanol, syrups and combinations thereof.

In liquid form, a masking composition may be prepared by mixing together a humectant component and a salt component. Then sufficient water, ethanol, syrups or 35 combinations thereof, may be added to the liquid mixture with mixing until reaching the desired volume.

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Other ingredients desirably delivered to the mouth may also be included at this stage of preparation.

Delivery in the form of suspensions may also be  
5 desirable. In that case, the suspensions may be prepared by conventional methods, such as admixing the thickener with water, and heating the mixture to a temperature within the range of from about 40°C to about 70°C. If the thickener is not water-soluble, a  
10 dispersion may form; if the thickener is water-soluble, a solution may form. Other ingredients desirably delivered to the mouth may be admixed with water. The masking composition (or the components thereof) may then be admixed with the thickener-water mixture until  
15 substantially uniformity is reached.

#### Solid Delivery Vehicles

##### Toothpastes and Dental Gels

20 When a masking composition according to this invention is desirably included in dentifrice, like a paste or a gel, for delivery into the mouth, the masking composition (or the individual components thereof) may  
25 be mixed with a breath freshening agent and/or anti-microbial agent, or a poly-valent metal cation to be introduced for the herein-described purposes, together with a dentifrice base, such as a paste or gel base.  
  
30 In the case of toothpaste or dental gel compositions, the toothpaste or dental gel delivery vehicle generally comprises water typically in an amount within the range of from about 20 to about 40% by weight. Polyethylene glycol, polypropylene glycol, glycerin and combinations  
35 thereof may also be present in the delivery vehicle to serve as a humectant or a binder in an amount within the range of from about 20 to about 60% by weight. The

- composition may often include a gelling agent or a thickening agent, such as a natural or synthetic gum or gelatin like hydroxyethyl cellulose, cellulose, methyl cellulose, glycerin, carboxypolymethylene, gelatin and
- 5 the like, and combinations thereof. Gelling agents or thickening agents may be used in an amount within the range from about 0.1 to about 25% by weight.
- Such toothpaste or dental gel compositions containing a
- 10 masking composition according to this invention may also contain conventional additives such as polishing agents, abrasive agents, desensitizing agents and the like.
- 15 In paste form, calcium carbonate or calcium dihydrate may be used as a polishing agent. In gel form, colloidal silica and/or alkali metal aluminosilicate complexes may be employed as a polishing agent since these materials have refractive indices similar to the
- 20 refractive indices of the gelling systems commonly used in dental gels. These polishing agents may be used in an amount up to about 25% by weight of the toothpaste or dental gel composition.
- 25 The present invention extends to methods for preparing such toothpaste or dental gel compositions. In these methods, the toothpaste or dental gel compositions may be prepared by admixing an effective amount of a masking composition and a toothpaste or dental gel base
- 30 using conventional methods and apparatus.

For instance, toothpastes or dental gels containing a masking composition according to this invention may be prepared by dispersing a gelling agent in a humectant

35 (either a humectant different from that employed in the masking composition or an additional portion of the humectant so employed in the masking composition),

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water or combinations thereof. This dispersion should be admixed with an aqueous solution of other ingredients, such as sweeteners, fluorine-providing compounds and the like. A polishing agent and a 5 flavoring agent may then be admixed therewith. Finally, the masking composition (or the individual component thereof) may be admixed therewith. The prepared toothpaste or dental gel composition may then be tubed or otherwise packaged. The liquid components 10 and solid components in such a product should be proportioned to form a creamy or gelled mass which may be extruded from a pressurized container, from a collapsible tube or from other suitable containing dispensers, such as pumps, though limited to those 15 pumps now commercially available.

**Chewable Confection**

When administration in a chewable form is desirable, 20 the compositions of this invention may be used to mask the astringent taste sensations experienced from such breath freshening agents and/or anti-microbial agents, or poly-valent metal cations, that are to be introduced into the mouth in such form. With chewable confection, 25 acceptable stability and quality, as well as good taste and organoleptic properties (*i.e.*, mouth feel) are desirable.

Chewable confection may be prepared by procedures well-known to those skilled in the art. See e.g., 30 Remington's Pharmaceutical Science, 18th ed. (1990), and B.W. Minifie, Chocolate, Cocoa and Confectionery Science and Technology, 424-25, 3rd ed., Van Nostrand Reinhold, New York (1989), the disclosure of each of 35 which is hereby incorporated herein by reference. The masking compositions of this invention may be admixed

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with the chewable confection base at an appropriate interval during preparation thereof.

Lozenges

5

Lozenges are intended to be convenient portable solid dosage forms. Lozenges may be produced in a variety of shapes such as flat, circular, octagonal and biconvex forms. Lozenge bases are generally in two forms: hard boiled candy lozenges and compressed tablet lozenges.

When a masking composition according to this invention is desirably included in a lozenge for delivery into the mouth, the lozenge composition may comprise for 15 instance, a breath freshening agent and/or an anti-microbial agent or an amount of a poly-valent metal cation effective to provide the chosen function of the lozenge and a masking composition according to this invention together with a lozenge base. The lozenge 20 composition should comprise an amount of the masking composition, which is effective to mask the astringent sensation experienced from such agents or cations when the lozenge is introduced into the mouth, and as it dissolves therein over time.

25

Lozenge formulations generally are well-known, as are their methods of preparation. See e.g., Remington's.

Chewing Gums

30

When a masking composition according to this invention is desirably delivered into the mouth in the form of a chewing gum, the masking composition (or the individual components thereof) may be mixed with a breath 35 freshening agent and/or an anti-microbial agent, or a poly-valent metal cation to be introduced for the herein-described purposes, together with a gum base.

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- The gum base may be any conventional water-insoluble gum base, which includes those gum bases utilized for chewing gums and bubble gums. Illustrative examples include, without limitation, natural and synthetic
- 5 polymeric materials like elastomers and rubbers. For example, polymeric materials suitable as gum bases include substances of vegetable origin such as chicle, crown gum, nispero, rosadinha, jelutong, perillo, niger gutta, tunu, balata, gutta-percha, lechi-capsi, sorva,
- 10 gutta kay and the like; synthetic elastomers such as butadiene-styrene copolymers, polyisobutylene, isobutylene-isoprene copolymers, polyethylene and the like; and combinations thereof.
- 15 Bulking agents suitable for use in gum bases include monosaccharides, disaccharides, polysaccharides, sugar alcohols, polydextrose, maltodextrins, minerals (such as calcium carbonate, talc, titanium dioxide, dicalcium phosphate and the like) and combinations thereof.
- 20 Bulking agents may be used in the gum base in an amount up to about 90% by weight of the final chewing gum composition, with an amount within the range of from about 40% to about 70% by weight being desirable and about 50% to about 65% being more desirable.
- 25
- The gum base may also contain a variety of traditional ingredients desirable to modify the texture and/or consistency or other properties of the final chewing gum product. These ingredients include plasticizers or
- 30 softeners like lanolin, palmitic acid, oleic acid, stearic acid, sodium stearate, potassium stearate, glyceryl triacetate, glyceryl lecithin, glyceryl monostearate, propylene glycol monostearate, acetylated monoglyceride, glycerine, polyethylene glycol,
- 35 glycerol, sorbitol, dioctyl-sodium sulfosuccinate, triethyl citrate, tributyl citrate, 1,2-propyleneglycol, mono-, di-, tri-acetates of glycerol

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- and the like, and combinations thereof. In addition, waxes (e.g., natural and synthetic waxes like petroleum waxes, such as polyurethane waxes, polyethylene waxes, paraffin waxes, microcrystalline waxes and fatty waxes), vegetable oils (e.g., coconut oil, palm kernel oil and the like), sorbitan monostearate, animal fats (e.g., tallow and the like), propylene glycol and the like may also be desirable to modify the texture and/or consistency or other properties of the final chewing gum product. Such plasticizers may be used in an amount up to about 25%, and preferably in an amount within the range of from about 1% to about 17%, by gum base.
- 15 The present invention extends to methods of making the chewing gum compositions. The masking composition may be incorporated into an otherwise conventional chewing gum using standard techniques and equipment known to those skilled in the art.
- 20 Chewing gum bases may be prepared by batch methods. Such methods generally involve mixing and melting the components of the gum base in kettle mixers in numerous stages, placing the resulting homogenous mass on trays 25 to be cooled, dried and thereafter transferred for incorporation into a chewing gum.
- Chewing gum bases may also be prepared by continuous processes, such as with a twin screw extruder. See 30 U.S. Patent Nos. 4,555,407; 5,045,325; and 5,135,760, the disclosures of each of which are hereby incorporated herein by reference.
- For example, an appropriate chewing gum base may be 35 chosen and heated to a temperature sufficiently high to soften the base without adversely affecting the physical and chemical properties and characteristics of

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the base. While the optimum temperatures may vary depending upon the composition of the chewing gum base, such temperatures may be readily determined by those skilled in the art without undue experimentation.

5

Conventionally, the gum base may be heated at a temperature within the range of from about 60°C to about 120°C for a period of time sufficient to soften and render it molten. For example, the chewing gum  
10 base may be heated under these conditions for a period of time of about thirty minutes just prior to being admixed incrementally with the remaining ingredients of the base. The chewing gum base may then be blended with the masking composition according to this  
15 invention (or the individual components thereof) and other ingredients desirably delivered to the mouth. Mixing may be continued until a substantially uniform chewing gum composition is obtained. Thereafter, the chewing gum composition may be formed into shapes  
20 desirable for chewing gum.

The chewing gum composition may be prepared with a liquid-filled center, which contains a breath freshening agent and/or an anti-microbial agent  
25 together with at least a masking composition according to this invention. Alternatively, the liquid-filled center of the chewing gum may contain one of the breath freshening agent and/or the anti-microbial agent or the masking composition, and the other contained in the  
30 chewing gum base itself, or vice versa.

#### Oral Hygiene Treatments

In the case where a masking composition according to  
35 this invention is desirably included in oral hygiene products, any conventional ingredient for oral hygiene treatments may be employed in the present invention,

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provided it is stable within the formulation and does not react adversely with any of the components of the formulations. Examples of such active oral hygiene ingredients include plaque-loosening and/or plaque-  
5 removing ingredients; ingredients which retard plaque growth; fluoride-releasing ingredients to fight tooth decay; ingredients to prevent or minimize gingivitis; breath freshening ingredients; anti-microbial agents to prevent or minimize microbial infection in the oral  
10 cavity; desensitizing agents; tartar-control agents and combinations thereof.

Plaque-loosening ingredients and/or plaque removing ingredients suitable for use herein as an oral hygiene  
15 treatment include abrasives such as dicalcium phosphate, silicon dioxide, calcium carbonate, aluminosilicates, sodium bicarbonate and the like, and combinations thereof.

20 Plaque-retarding ingredients suitable for use herein as an oral hygiene treatment include the combination of thymol, menthol, eucalyptol and methyl salicylate (the active essential oil ingredients in LISTERINE® antiseptic mouth rinses, which mouth rinses are readily  
25 available commercially and are manufactured by Warner-Lambert Co., Morris Plains, New Jersey), quaternary ammonium compounds like alkyl pyridinium halides (e.g., cetyl pyridinium chloride, benzethonium chloride and benzalkonium chloride and the like), triclosan (2,4,4'-  
30 trichloro-2-hydroxydiphenyl ether) and combinations thereof.

Fluoride-releasing ingredients are compounds characterized by their ability to release fluoride ions  
35 or fluoride-containing ions. Due to chemical instability of many fluoride-releasing compounds at acid pH values, these compounds are generally used in

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alkaline delivery vehicles to provide their intended treatment. Suitable fluoride-releasing compounds for use herein as an oral hygiene treatment include inorganic fluoride salts, such as water-soluble alkali metal salts, alkaline earth metal salts and heavy metal salts, such as sodium fluoride, potassium fluoride, stannic fluoride, stannous fluoride, barium fluoride, sodium fluorosilicate, ammonium fluorosilicate, sodium fluorozirconate, sodium monofluorophosphate, aluminum 5 mono- and di-fluorophosphates, fluorinated sodium calcium pyrophosphate and combinations thereof.

Anti-gingivitis ingredients suitable for use herein as an oral hygiene treatment include the combination of thymol, menthol, eucalyptol and methyl salicylate (the active essential oil ingredients in LISTERINE® antiseptic mouth rinses), and bisbiguanides (like chlorhexidine).

Breath fresheners suitable for use herein as an oral hygiene treatment include zinc salts (like zinc chloride, zinc gluconate, zinc salicylate and the like), copper salts (like copper gluconate and the like) and combinations thereof.

25 Anti-microbial agents suitable for use herein as an oral hygiene treatment include the combination of thymol, menthol, eucalyptol and methyl salicylate (the active essential oil ingredients in LISTERINE® antiseptic mouth rinses), benzoic acid and derivatives thereof, quaternary ammonium compounds like those noted above, bisbiguanides, triclosan and combinations thereof.

35 Desensitizing ingredients suitable for use herein as an oral hygiene treatment include stannous fluoride, citric acid and salts (e.g., sodium) thereof, potassium

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nitrate, strontium chloride, calcium phosphate and combinations thereof.

- Tartar-control agents suitable for use herein as an
- 5 oral hygiene treatment include stannous fluoride, pyrophosphates like tetra-sodium pyrophosphate, sodium pyrophosphate, calcium pyrophosphate and potassium pyrophosphate.
- 10 Hydrogen peroxide and/or sodium bicarbonate may also be included in the oral hygiene products containing the masking composition of this invention to provide an oral hygiene treatment, without the astringency associated with many oral hygiene ingredients.

15

Additives

- In any of the forms of delivery vehicle in which the masking compositions of this invention may be included,
- 20 certain additives may also be included. Examples of such additives include orally-acceptable solvents, sweeteners, flavoring agents, anti-foaming agents, humectants, lubricants, dyes or coloring agents, preservatives or shelf-life enhancing agents,
- 25 organoleptic consistency modifiers or bioadhesives (like suspending agents, gelling or thickening agents) and combinations thereof.

- Orally-acceptable solvents such as ethyl alcohol,
- 30 propylene glycol, polyethylene glycol and the like may be used to dissolve the flavoring agents and the active oral hygiene ingredients. In general, orally-acceptable solvents may be used in an amount up to about 30% by weight, with about 2% to about 5% being
- 35 desirable.

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Surfactants may also be used herein to act as solubilizers. Surfactants desirably reduce surface tension when dissolved in water or reduce interfacial tension between two liquid components or a liquid component and a solid component. The surfactants may be nonionic surfactants, anionic surfactants, cationic surfactants, amphoteric surfactants and combinations thereof. Suitable surfactants include, but are not limited to, those in the family known as TWEENS and PLURONICS, and may also be found listed and described in McCutcheon's Emulsifiers and Detergents, North American ed. (1988).

It may be desirable to use sweetening agents (sweeteners) in any of the forms of delivery vehicles in which the masking composition of this invention may be included. While certain sweeteners may be more desirable when used in one form of delivery vehicle than another, such sweeteners well known in the art, including both natural and alternative sweeteners, may be employed herein with one of ordinary skill in the art making appropriate choices of among those sweeteners. The sweeteners suitable for use herein may be selected from water-soluble sweeteners, water-soluble alternative sweeteners, water-soluble sweeteners derived from naturally-occurring water-soluble sweeteners, dipeptide-based sweeteners, protein-based sweeteners, sugar alcohols and combinations thereof.

Without being limited to particular sweeteners, representative classes and examples of such include:

(a) water-soluble sweeteners such as monosaccharides, disaccharides and polysaccharides [like xylose, ribose, glucose (dextrose), mannose, galactose, fructose (levulose), sucrose (sugar) and maltose], invert sugar

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(a mixture of fructose and glucose derived from sucrose), partially hydrolyzed starch, corn syrup solids, dihydrochalcones, monellin, steviosides, glycyrrhizin and combinations thereof;

5

- (b) water-soluble alternative sweeteners, such as saccharin and salts (e.g., sodium, calcium or potassium) thereof, cyclamate salts (e.g., sodium or calcium cyclamate salts), sodium, ammonium or calcium salts of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide (known under the designation ACESULFAME-K) and combinations thereof;
- 10 15 (c) dipeptide-based sweeteners, such as L-aspartic acid derived alternative sweeteners like  $\alpha$ -L-aspartyl-L-phenylalanine methyl ester (commercially available from the Nutrasweet Company under the trademark ASPARTAME<sup>®</sup>),  $\alpha$ -L-aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alanin-amide hydrate (known under the designation ALITAME), and methyl esters of  $\alpha$ -L-aspartyl-L-phenylglycine,  $\alpha$ -L-aspartyl-L-2,5-dihydrophenyl-glycine,  $\alpha$ -L-aspartyl-2,5-dihydro-L-phenylalanine,  $\alpha$ -L-aspartyl-L-(1-cyclohexen)-alanine and combinations thereof;
- 20 25

- (d) water-soluble sweeteners derived from naturally occurring water-soluble sweeteners, such as chlorinated sucrose derivatives -- e.g., chlorodeoxysucrose or chlorodeoxygalactosucrose (known under the designation SUCRALOSE);

- 30 (e) protein-based sweeteners, such as thaumatooccus danielli (Thaumatin I and II); and

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- (f) sugar alcohols, such as sorbitol, xylitol, inositol, maltitol, mannitol and combinations thereof.

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Of course, combinations of sweeteners across these classifications may also be used.

A sufficient amount of sweetener should be used to  
5 provide the level of sweetness desired in the particular composition. The amount of sweetener chosen may be within the range from about 0.0025% to about 90% by weight, depending of course on the particular sweetener, its physical properties and characteristics  
10 and the level of sweetness desired.

Flavoring agents may also be used herein, including natural flavors and natural flavor mimetics. Indeed, any flavoring agent generally recognized as safe for  
15 food and drug application may be used herein. Suitable flavoring agents include mints (such as peppermint and spearmint), anethole, citrus flavors (such as orange and lemon), vanilla, cinnamon, various fruit flavors (such as cherry and apple) and the like. The amount of  
20 flavoring agent may vary depending of course on the specific flavoring agent, its physical properties or characteristic and the intensity of the flavor imparted. Flavor enhancers, such as monoammoniumglycyrrhizinate, may also be advantageously  
25 employed herein.

Typically, the amount of sweetener and/or flavoring agent employed in the compositions of this invention is a matter of preference subject to such factors as the  
30 type of composition and delivery vehicle thereof, the rapidity of delivery of the particular sweetener and/or flavoring agent employed and the intensity desired.

Anti-foaming agents, such as dimethyl polysiloxane, may  
35 be advantageously used herein. When used, the anti-foaming agent should be employed in an amount up to

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about 0.2% by weight, with about 0.01% to about 0.1% being desirable.

Suitable humectants useful herein include glycerin,  
5 sorbitol, mono- and di-glycerides of fatty acids,  
propylene glycol, pectins and the like, and  
combinations thereof. When used, humectants may be  
employed in an amount within the range of from about 1%  
to about 35% by weight.

10

Suitable lubricants include lipids (like oils and  
fats), euricamide, waxes and phospholipids (like  
unsaturated and saturated fatty acids and salts  
thereof, such as aluminum, calcium, magnesium and tin  
15 stearates), silicones and the like may be used in an  
amount within the range of from about 0.001 to about  
10% by weight.

Suitable dyes or coloring agents may also be  
20 advantageously employed herein. When used, these dyes  
or coloring agents include titanium dioxide, silicon  
dioxide, coloring agents, such as azo-dyes and other  
dyestuffs and pigments as iron oxides, titanium  
dioxides, natural dyes and the like may be used in an  
25 amount within the range of from about 0.001 to about  
10% based upon the weight of the composition.

Preservatives or shelf-preservation agents, such as  
butylated hydroxyanisole (BHA), butylated  
30 hydroxytoluene (BHT), parabens like methyl paraben and  
propyl paraben, tocopherols and the like, and  
combinations thereof may be employed herein. When  
used, the preservatives should generally be present in  
an amount up to about 1% by weight, with about 0.05% to  
35 about 0.5% being desirable.

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Suitable organoleptic consistency modifiers or bioadhesives, include suspending agents, gelling agents or thickening agents such as cellulosics like methylcellulose, carrageenans like alginic acid and 5 derivatives thereof, xanthan gums, gelatin, acacias and microcrystalline cellulose. Such organoleptic consistency modifiers may be used herein in an amount up to about 20% by weight, with about 1% to about 15% being desirable.

10

The following examples are provided for illustrative purposes only.

Examples

15

Example 1

To prepare a masking composition according to the present invention, about 1 gram of sodium chloride as a 20 salt was added to about 350 grams of glycerin as a humectant with stirring at room temperature. This masking composition may be stored indefinitely, and may also be used as a master batch for oral hygiene products containing the masking compositions.

25

Example 2

In this example, three mouth rinse samples were prepared, with each containing a component that is 30 known to impart an astringent sensation to mouth. In the first sample, zinc gluconate (about 6.7 grams/liter) was chosen; in the second sample, benzoic acid (about 3 grams/liter) was chosen; and in the third sample, both zinc gluconate (about 6.7 grams/liter) and 35 benzoic acid (about 3 grams/liter) were chosen. The mouth rinse base for each sample was prepared from the following components: peppermint oil (about 1.5

grams/liter), spearmint oil (about 0.4 grams/liter), anethole (about 0.1 grams/liter), PLURONIC F-127 (about 12 grams/liter), TWEEN 20 (about 2 grams/liter) and monoammoniumglycyrrhizinate (about 0.7 grams/liter), in 5 addition to the astringency-imparting component. Water was then added to bring these components to a volume of about 1 liter.

The pH value of each of the samples was adjusted to 10 about 3.8 through the addition of either 1 N NaOH or 1N HCl. To the first sample, about 6.5 mls of 1N HCl was added to bring the pH value from its initial value of about 4.9 to a value of about 3.8. This sample was observed to be cloudy. To the second sample, about 5 15 mls of 1N NaOH was added to bring the pH value from its initial value of about 3.1 to a value of about 3.8. This sample was also observed to be cloudy. The third sample was determined to have a pH value of about 3.88; hence, no adjustment to the pH value was made. This 20 sample was also observed to be cloudy.

An astringency rating system was established whereby a rating of zero indicates no detectable astringent sensation, and as one proceeds toward the other end of 25 the scale an astringent sensation in an increasingly greater amount was detected.

A subject rinsed with about 30 mls of each of these mouth rinse samples for a period of time of about 15 30 seconds, rinsing the mouth with water between samples and allowing an adequate period of time to elapse between sample rinses to minimize the opportunity of a carry over effect between samples. The subject judged the first sample to have an astringency rating of 8.5; 35 the second sample to have an astringency rating of 8; and the third sample to have an astringency rating of 7.5.

- 25 -

Three mouth rinse samples were prepared as above, except that to each was added prior to dilution to 1 liter the masking composition of the present invention -- e.g., about 1 gram of sodium chloride and about 350 5 grams of glycerin.

The pH value of each of the masking composition-containing samples was adjusted to about 3.8 through the addition of either 1 N NaOH or 1N HCl. To the 10 first masking composition-containing sample, about 7.5 mls of 1N HCl was added to bring the pH value from its initial value of about 5.1 to a value of about 3.9. To the second masking composition-containing sample, about 3.5 mls of 1N NaOH was added to bring the pH value from 15 its initial value of about 3.2 to a value of about 3.8. This sample was observed to be cloudy. To the third masking composition-containing sample, about 4 mls of 1N HCl was added to bring the pH value from its initial value of about 4 to a value of about 3.8. This sample 20 was also observed to be cloudy.

A subject then rinsed with about 30 mls of each of these masking composition-containing mouth rinse samples for a period of time of about 15 seconds, 25 rinsing the mouth with water between samples and allowing an adequate period of time to elapse between sample rinses to minimize the opportunity of a carry over effect between samples. The subject judged the first masking composition-containing sample to have an 30 astringency rating of 2.5; the second masking composition-containing sample to have an astringency rating of 1; and the third masking composition-containing sample to have an astringency rating of 4. 35 The astringent sensation of the mouth rinse samples was thus seen to decrease to the masking composition.

Example 3

In this example, two mouth rinse samples were prepared based upon known commercial mouth rinses. In each

5 sample, zinc gluconate (about 6.7 grams/liter) was included as a breath freshening agent. The mouth rinse base for the first sample was prepared from the following components: glycerin (about 70 grams/liter), peppermint oil (about 1.5 grams/liter), spearmint oil

10 (about 0.4 grams/liter), anethole (about 0.1 grams/liter), PLURONIC F-127 (about 7 grams/liter) and u.s.p alcohol (150 mls), in addition to the breath freshening agent. The mouth rinse base for the second sample was prepared from the following components:

15 glycerin (about 160 grams/liter), peppermint oil (about 1.5 grams/liter), spearmint oil (about 0.4 grams/liter), anethole (about 0.1 grams/liter), PLURONIC F-127 (about 7 grams/liter) and u.s.p alcohol (150 mls), in addition to the breath freshening agent.

20 Water was then added to each sample bring these components to a volume of about 1 liter.

The pH value of each sample was adjusted to about 3.8 through the addition of 1N HCl. To the first sample,

25 about 7.5 mls of 1N HCl was added to bring the pH value from its initial value of about 5.6 to a value of about 3.8. To the second sample, about 8 mls of 1N HCl was added to bring the pH value from its initial value of about 5.7 to a value of about 3.8.

30 A subject rinsed with about 30 mls of each of these mouth rinse samples for a period of time of about 15 seconds, again rinsing the mouth with water between samples and allowing an adequate period of time to

35 elapse between sample rinses to minimize the opportunity of a carry over effect between samples. The subject judged the first sample to have an

astringency rating of 7.5, and the second sample to have an astringency rating of 5.5.

- Two mouth rinse samples were prepared as above, except
- 5 that to each was added prior to dilution to 1 liter the masking composition of the present invention -- e.g., about 1 gram of sodium chloride and about 350 grams of glycerin -- from Example 1, supra.
- 10 The pH value of each of these masking composition-containing samples was adjusted to about 3.8 through the addition of about 9 mls of 1N HCl. The addition of the HCl to the first masking composition-containing sample brought the pH value from its initial value of about 5.8 to a value of about 3.8. The addition of the HCl to the second masking composition-containing sample brought the pH value from its initial value of about 5.8 to a value of about 3.8.
- 15
- 20 A subject rinsed with about 30 mls of these masking composition-containing mouth rinse samples for a period of time of about 15 seconds, rinsing the mouth with water between samples and allowing an adequate period of time to elapse between sample rinses to minimize the opportunity of a carry over effect between samples.
- 25 The subject judged each of the first and the second masking composition-containing sample to have an astringency rating of 2.5.
- 30 The astringency of the mouth rinse samples that already contain a certain amount of glycerin was seen to decrease due to the masking composition. In addition, the mouth rinses containing the masking compositions of this invention were observed to foam less and have a
- 35 slightly thicker mouth feel without a slick feeling on the teeth than conventional mouth rinses containing

glycerin, but not the masking compositions of this invention.

These examples are presented for illustrative purposes,  
5 only. Variations and equivalents of the masking composition so illustrated exist both as to their formulations and as to their form of delivery vehicle. These variations and equivalents should provide suitable, if not comparable results, when viewed in  
10 connection with the results obtained from the above examples. Accordingly, such variations and equivalents are also intended to be encompassed by the claims which follow hereinafter.

WHAT IS CLAIMED IS:

1. A composition capable of masking astringent taste sensations, comprising the combination of a humectant component and a salt component.
2. The composition according to claim 1, wherein the humectant component is selected from the group consisting of glycerin, sorbitol, propylene glycol, mono- and di-glycerides of fatty acids, pectins and combinations thereof.
3. The composition according to claim 1, wherein the salt component is selected from the group consisting of sodium chloride, potassium chloride, sodium bicarbonate, potassium bicarbonate, sodium carbonate, potassium carbonate and combinations thereof.
4. The composition according to claim 1, wherein the ratio of the humectant component to the salt component in said composition is within the range of from about 99.99-99.00% to about 0.01-1.0%.
5. The composition according to claim 1, wherein the astringent taste sensations are imparted by oral hygiene ingredients selected from the group consisting of breath freshening agents, anti-microbial agents and combinations thereof.
6. The composition according to claim 5, wherein said breath freshening agents are selected from the group consisting of zinc chloride, zinc salicylate, zinc gluconate, silver nitrate, silver gluconate and combinations thereof.
7. The composition according to claim 5, wherein said anti-microbial agents are selected from the group

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consisting of benzoic acid and derivatives thereof, quaternary ammonium compounds, bisbiguanides and combinations thereof.

8. The composition according to claim 1, wherein the astringent taste sensations are imparted by poly-valent metal cations.

9. The composition according to claim 8, wherein said poly-valent metal cations are selected from the group consisting of zinc chloride, zinc salicylate, zinc gluconate, silver nitrate, silver gluconate and combinations thereof.

10. A method of using the combination of a humectant component and a salt component to mask astringent taste sensations imparted by a member selected from the group of oral hygiene ingredients consisting of breath freshening agents, anti-microbial agents and poly-valent metal cations thereto, said method comprising the steps of:

(a) providing the combination of a humectant component and a salt component to an oral hygiene composition containing an oral hygiene ingredient which imparts an astringent taste sensation, to form an astringency-masked oral hygiene composition; and

(b) introducing the composition of (a) into the mouth,

whereby the humectant-salt combination masks astringency associated with the oral hygiene ingredient.

11. A mouth rinse composition capable of providing an effective oral hygiene treatment to the mouth with minimal astringent taste sensation, comprising:

(a) an effective amount of active oral hygiene ingredients selected from the group consisting of

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breath freshening agents, anti-microbial agents, polyvalent metal cations and combinations thereof;

(b) a composition capable of masking astringent taste sensations, comprising

(i) a humectant component, and

(ii) a salt component; and

(c) a vehicle suitable for delivering said masking composition and said active oral hygiene ingredients into the mouth.

12. A dentifrice composition capable of providing an effective oral hygiene treatment to the mouth with minimal astringent taste sensations, comprising:

(a) an effective amount of active oral hygiene ingredients selected from the group consisting of breath freshening agents, anti-microbial agents, polyvalent metal cations and combinations thereof;

(b) a composition capable of masking astringent taste sensations, comprising

(i) a humectant component, and

(ii) a salt component; and

(c) a vehicle suitable for delivering said masking composition and said active oral hygiene ingredients into the mouth.

13. The mouth rinse composition according to claim 11, wherein said masking composition is employed in said composition in an amount within the range of from about 20% to about 50% by weight of the mouth rinse composition.

14. The mouth rinse composition according to claim 13, wherein said masking composition is employed in said composition in an amount of about 35% by weight of the mouth rinse composition.

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15. The mouth rinse composition according to claim 11, further comprising: (d) additional active oral hygiene ingredients selected from the group consisting of plaque-loosening and/or plaque-removing ingredients, ingredients which retard plaque growth, fluoride-releasing ingredients to fight tooth decay; ingredients to prevent or minimize gingivitis and combinations thereof.

16. The mouth rinse composition according to claim 11, further comprising: (d) additives selected from the group consisting of orally-acceptable solvents, sweeteners, flavoring agents, anti-foaming agents, humectants, lubricants, coloring agents, preservatives, organoleptic consistency modifiers and combinations thereof.

17. The mouth rinse composition according to claim 15, further comprising: (e) additives selected from the group consisting of orally-acceptable solvents, sweeteners, flavoring agents, anti-foaming agents, humectants, lubricants, coloring agents, preservatives, organoleptic consistency modifiers and combinations thereof.